

REMARKS

Applicants have received and carefully reviewed the Advisory Action dated July 10, 2002. Applicants have amended claims 1, 3, 12 and 15 in this paper. An Amendment After Final was filed by Applicants, amending claims 1 and 3, but the Examiner refused to enter the Amendment After Final in the Advisory Action dated July 10, 2002. Applicants hereby request that the above amendments be entered in lieu of the Amendment After Final.

The Examiner rejects claims 1-9, 11-15 and 21 under 35 U.S.C. §102(e) as being anticipated by Heck in U.S. Patent No. 6,083,207.

Claim 1 has been amended to include greater detail of the valve sleeve, which is distinct from the valve body, sheath, and medical device. Heck fails to teach a valve sleeve adapted to allow introduction of a medical device into a lumen of the valve sleeve and extending proximal of the means for compressing the valve sleeve. The valve sleeve, as claimed, enables better fluid containment by limiting fluid flow through the valve sleeve lumen until after a medical device is positioned within the valve sleeve lumen. The valve sleeve lumen may be sized such that, once a particular medical device is positioned, the valve sleeve lumen may be occluded by the medical device to reduce fluid flow after the valve sleeve is released from compression. Thus, the device recited in claim 1 can perform two functions, first, as a non-return valve, and second, as a coupling device for coupling medical devices or catheters into a peel-away sheath.

The Examiner has indicated that the medical device suggested by Heck is a compressible valve sleeve as recited in Applicants' claim 1. It appears the Examiner is referring to a dilator 300 as shown in Figure 2 or, alternatively, to dilators as noted by Heck in column 1 lines 13-24. After careful review, it does not appear to Applicants that there is any suggestion that the dilator 300 or other device inserted through the lips 56 suggested by Heck is compressible in the way

recited in Applicants' claim 1. Indeed, much of the prior art teaches away from using a compressible catheter or tube, since such a device would likely lack the pushability often needed in vasculature catheterization procedures due to a tendency to kink when compressed (hence the inclusion of braided support member, for example, in many catheter designs). Rather than finding prior art suggesting a compressible valve sleeve, the Examiner appears to have read the limitation from the claim into the prior art.

In light of the above amendments and remarks, Applicants believe that independent claim 1 and dependent claim 2 are clearly patentable over Heck.

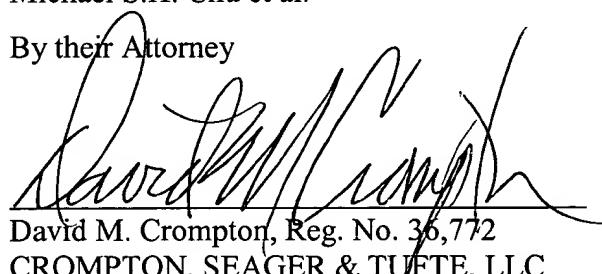
Independent claims 3, 12 and 15, as amended, all likewise recite compressible sleeves or compressible valve sleeves adapted to receive a medical device or catheter. Therefore, in light of the above amendments and remarks, Applicants also believe that independent claims 3, 12 and 15, along with dependent claims 4-9, 11, 13-14 and 21, are likewise patentable over Heck.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims, namely claims 1-9, 11-15 and 21, are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney



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Date: 7/17/02



Version with Markings to Show Changes Made

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In the Claims:

Claims 1, 3, 12 and 15 have been amended as follows:

1. (Once Amended) A valve for a tubular peel-away sheath having a lumen therethrough comprising:

a valve body having a lumen therethrough;

means for preferentially breaking said valve body along a predetermined location in response to applied force, such that said valve body lumen splits open upon breaking;

means for coupling said valve body to said peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen;

means for receiving a compressible valve sleeve [having a lumen therethrough for coupling said valve sleeve lumen to said valve body lumen]; [and]

a compressible valve sleeve having a proximal end, a distal end, and a lumen adapted to receive a distal portion of a medical device; and

means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through said valve and valve sleeve lumen, said proximal end of said compressible valve sleeve extending proximal of said means for compressing said valve sleeve.

3. (Twice Amended) A breakaway valve for a tubular peel-away sheath, said sheath having an external surface, a lumen, and a proximal end comprising:

means for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end, wherein said means for reversibly restricting fluid flow includes a compressible valve sleeve and means for compressing said valve sleeve, said valve sleeve having a proximal end and a distal end and a lumen therethrough, the proximal end of said valve sleeve extending proximal of said means for reversibly restricting fluid flow and adapted to admit a catheter distal end into said valve sleeve lumen; and

means for breaking apart said fluid flow restricting means responsive to applied force[; and

means for admitting a catheter distal end into said valve].

12. (Once Amended) An introducer sheath assembly for introducing a catheter distally into a human body comprising:

a tubular, distal introducer sheath having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip for preferentially tearing said sheath along said strip;

a tubular, compressible [flexible], proximal valve sleeve having a proximal region, a distal region, and a lumen therethrough; and

a valve body having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve

body having a seat for mating to said proximal valve sleeve distal region, said valve body including a pinch member for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve; wherein said proximal region of said proximal valve sleeve extends proximal of said pinch member and is adapted to receive a medical device.

15. (Once Amended) A breakaway valve body for restricting flow from a peel-away introducer sheath having a proximal region and a lumen therethrough comprising:

a breakaway distal portion having a lumen therethrough for receiving said introducer sheath proximal region; and

a proximal portion including two opposed valve body members, at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed members move together relative to each other to reach said closed position, wherein said flexible sleeve has a lumen therethrough adapted to receive a medical device, said flexible sleeve having a proximal end, and a distal end, said proximal end extending proximal of said body members, said sleeve being compressible, and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position.